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Re-evaluation Note REV2017-14

Re-evaluation Project Plan for Dodecylguanidine Hydrochloride

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Background

In Canada, dodecylguanidine hydrochloride is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). PMRA re-evaluates registered pesticides to determine whether the use of these products continues to be acceptable in terms of value, human health and the environment according to current standards.

Dodecylguanidine hydrochloride is registered as a biocide for use in industrial process fluids of pulp and paper mills, recirculating cooling water towers and air washers, as well as a material preservative for pulp and paper products. As of 22 March 2017, there are currently one technical grade product and six end-use products containing dodecylguanidine hydrochloride registered in Canada. All end-use products are co-formulated with either N-alkyl dimethyl benzyl ammonium chloride or methylene bis(thiocyanate). All products are formulated as solutions.

Under the authority of section 16 of the *Pest Control Products Act*, all registrants of dodecylguanidine hydrochloride were notified of the initiation of the re-evaluation of dodecylguanidine hydrochloride. Following this, the registrant of dodecylguanidine hydrochloride technical grade active ingredient in Canada indicated support of all uses included on the labels of end use products in Canada.

The re-evaluation project plan below outlines the timeline, the anticipated area(s) of focus for the risk assessments, and the data requirements for the re-evaluation of dodecylguanidine hydrochloride.

Re-evaluation Project Plan

Anticipated Re-evaluation Timeline

The re-evaluation of dodecylguanidine hydrochloride is defined as a Category 1 as described in Regulatory Directive DIR2016-04, *Management of Pesticides Re-evaluation Policy*, which was adopted on 1 December 2016. However, because this re-evaluation was initiated prior to the publication of DIR2016-04, the proposed re-evaluation decision for dodecylguanidine hydrochloride is anticipated to be published for consultation by July 2019. The re-evaluation timeline may be updated if, during the risk assessment, PMRA identifies additional areas of focus that should be considered.

Human Health Risk Assessment

New assessments will be conducted for toxicology and occupational exposure.

Environmental Risk Assessment

Existing assessments with minor updates are considered to be adequate to support the re-evaluation of dodecylguanidine hydrochloride.

Value

The value of dodecylguanidine hydrochloride will be considered. The viability of alternatives will be examined for certain uses if risks of concern requiring mitigation are identified.

Data Requirements

PMRA has identified the need for the technical registrant(s) to provide data for dodecylguanidine hydrochloride related to toxicology. Relevant data/studies have been requested from the technical registrant. A summary of the data call-in is found in PMRA's Public Registry, found online at http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#ppid. For a list of data categories that have been required, see Appendix I. In addition, information regarding the registered use pattern has been requested from the registrants, to inform the risk assessments.

Additional Information

PMRA documents can be found in the Pesticides and Pest Management section of Health Canada's website at healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service:

Phone:	1-800-267-6315	within Canada, or
	1-613-736-3799	outside Canada (long distance charges apply)
Fax:	1-613-736-3798	
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Appendix I Data Required Under Subsection 19(1) of the *Pest Control Products Act* for the Re-evaluation of Dodecylguanidine Hydrochloride

Toxicology Data

4.2	Acute Studies
4.2.1	Acute Oral
4.2.2	Acute Dermal
4.2.3	Acute Inhalation
4.2.4	Primary Eye Irritation
4.2.5	Primary Dermal Irritation
4.2.6	Dermal Sensitization
4.3.5	Short-term Dermal (21/28-day)
4.4.1	Chronic (rodent)
4.4.2	Oncogenicity (rodent species 1) *[DACO 4.4.1 and 4.4.2 may be submitted as a combined study under DACO 4.4.4: Combined Chronic/Oncogenicity (rodent)]*
4.4.3	Oncogenicity (rodent species 2)
4.5.1	Multigeneration Reproduction (rodent)
4.5.3	Prenatal Developmental Toxicity (non-rodent)
4.5.4	Genotoxicity: Bacterial Reverse Mutation Assay
4.5.5	Genotoxicity: In vitro Mammalian Cell Assay
4.5.6	Genotoxicity: In vitro Mammalian Clastogenicity
4.5.7	Genotoxicity: In vivo Cytogenetics
4.5.9	Metabolism/Toxicokinetics in Mammals (laboratory animals)